SEP – 3 2009

K091366

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for Insu*flow*® DewHeart™

SUBMITTER'S NAME:	LEXION Medical LLC
ADDRESS:	5000 Township Parkway St. Paul, MN 55110
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-361-8041
FAX NUMBER:	651-351-8001
DATE OF SUBMISSION:	1 May 2009

1. **Identification of device**
   Proprietary Name: Insu*flow*® DewHeart™
   Common Name: Blower/Mister Gas Conditioner
   Classification Status: Class II per regulations 880.5475 Product Code FQH
   Class II per regulations 884.1730 Product Code HIF

2. **Equivalent devices**
   LEXION Medical believes that Insu*flow*® DewHeart™ is substantially equivalent to the following devices:
   Insu*flow*®, K063546
   CarbonAid, K052125
   CTS Blower Mister, K983135
   Insu*flow*® DewHeart™ is technically the same device as the Insu*flow*® gas conditioner insufflator accessory device cleared under 510(k) K063546 and has essentially the same intended use as the predicate devices.

3. **Description of the Device**
   The Insu*flow*® DewHeart™ device is a single use blower/mister device that attaches to the outlet port of the Insu*flow*® controller with regulated CO_2 source and is designed to warm and humidify the CO_2 gas stream prior to introduction into the cardiovascular cavity. The Insu*flow*® DewHeart™ device consists of a disposable filter heater/humidifier tubing set and a control module that houses the control and safety circuits for the system.

   Regulated CO_2 gas flows into the Insu*flow*® DewHeart™ device, through the in-line filter, continues along the tube to enter the Insu*flow*® DewHeart™ device cassette that contains the heating element and humidification media, through a nozzle/wand for directional localization of a CO_2 gas stream entry into the patient's surgical cavity.

4. **Intended use**
The Insu*flow*® DewHeart™ is a Blower/Mister Gas conditioner device for use in cardiovascular surgical procedures intended to heat, humidify and filter a CO_2 gas stream for introduction into the surgical cavity to improve visibility and reduce the risk of air embolism.

5. **Technological characteristics, comparison to predicate device.**
Technically, the Insu*flow*® DewHeart™ is the same as the Insu*flow*® cleared for market in 510(k) K063546 and essentially equivalent to the other two predicates. The indications for use for the Insu*flow*® DewHeart™ are patterned after the predicate devices and supported by an extensive collection of literature references.

6. **Discussion of performance testing.**
Extensive performance testing has been conducted to assure that the Insu*flow*® DewHeart™ performs in accordance with its specifications and applicable standards. Details of the Insu*flow*® testing were provided in 510(k) K063546 and are summarized in Section 5.

7. **Conclusion**
Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that Insu*flow*® DewHeart™ is substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP - 3 2009

Lexion Medical, LLC
c/o Mr. Bernard Horwath
Consultant to Lexion Medical, LLC
5000 Township PKWY
St. Paul, MN 55110

Re: K091366
Trade/Device Name: Insuflow Dewheart
Regulation Number: 21 CFR 884.1730
Regulation Name: Jet, Lavage, Insufflator, laparoscopic
Regulatory Class: Class II (two)
Dated: August 27, 2009
Received: August 28, 2009

Dear Mr. Horwath

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vorhees

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K091366

Device Name: Insu*flow*® DewHeart™

Indications for Use:

The Insu*flow*® DewHeart™ is a Blower/Mister Gas conditioner device for use in cardiovascular surgical procedures intended to heat, humidify and filter a CO_2 gas stream for introduction into the surgical cavity to improve visibility and reduce the risk of air embolism.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091366

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)